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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,390	08/21/2001	William Peter Van Antwerp	G&C 130.15-US-D1	8366

7590 09/11/2003  
Attention of William J. Wood  
Gates & Cooper LLP  
Howard Hughes Center  
6701 Center Drive West, Suite 1050  
Los Angeles, CA 90045

EXAMINER

WINAKUR, ERIC FRANK

ART UNIT PAPER NUMBER

3736

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/934,390

Applicant(s)

VAN ANTWERP ET AL. *ad*

Examiner

Eric F Winakur

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 21 - 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of the claimed subject matter is unclear. Although it appears that Applicant intends to claim a system comprising a biocompatible polymer matrix and an amplification component incorporated within the matrix, the claims recite "A biocompatible polymer matrix comprising an amplification component ...". As such, the claims appear to only be limited by details of the amplification component since only the amplification component is defined in the body of the claim. The dependent claims that recite limitations of the biocompatible polymer matrix are not further limiting, as they do not provide limitations of the amplification component. With regard to claim 34, it is unclear how the "mesh" is meant to relate to the other claimed elements.

### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 28 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim appears to improperly include a

Art Unit: 3736

living being as part of the claimed subject matter. The claim should recite that the matrix is "adapted to be" implanted subdermally to avoid this problem.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 21 - 34, 36 - 40, 42 - 47, 49, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by James et al. (GB 2 284 809 A - cited by Applicant). As detailed in paragraph 2 above, the claims appear to cover only the amplification component. James et al. teach a fluorescent phenylboronic acid for detecting saccharides that includes all of the claimed features of the amplification component. Without positively claiming the amplification component incorporated within the polymer matrix, James et al. is considered to meet the claimed subject matter.

***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 3736

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 21, 24, and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 6,011,984. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the patent are drawn to an implantable polymer matrix and an amplification component. The claims of the instant application are broader than those of the patent. Thus, any implantable system meeting the limitations of the patent would necessarily meet those of the instant application. With regard to claim 26, it is considered to be within the skill level of the art to implement the amplification system of the patent with any desired shape, including those set forth in the claim of the application.

9. Claims 21, 24, and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 12, and 31 of U.S. Patent No. 6,002,954. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the patent are drawn to an implantable polymer matrix and an amplification component. The claims of the instant application are broader than those of the patent. Thus, any implantable system meeting the limitations of the patent would necessarily meet those of the instant application. With regard to claim 26, it is considered to be within the skill level of the art to implement the amplification system of the patent with any desired shape, including those set forth in the claim of the application.

***Allowable Subject Matter***

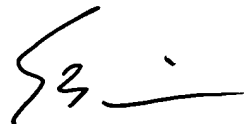
10. The following is a statement of reasons for the indication of allowable subject matter: The amplification component of James et al. is not capable of covalent attachment to a polymer matrix and does not experience a decrease in signal intensity by the binding of the analyte.

11. Claims 35, 41, and 48 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F Winakur whose telephone number is 703/308-3940. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703/308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0858.



Eric F Winakur  
Primary Examiner  
Art Unit 3736

8 September 2003